

CLAIMS:

1. A pharmaceutical composition for stabilizing vulnerable plaques in blood vessels of a subject in need of such a stabilization, for preventing or treating restenosis in diabetic patients, or for the prevention or reduction of vascular access dysfunction in association with the insertion or repair of an indwelling shunt, fistula or catheter in a subject in need thereof, comprising N-{5-[4-(4-methyl-piperazino-methyl)-benzoylamido]-2-methylphenyl}-4-(3-pyridyl)-2-pyrimidine-amine or a pharmaceutically acceptable salt or crystal form thereof, together with one or more pharmaceutically acceptable diluents or carriers therefore.
2. Use of N-{5-[4-(4-methyl-piperazino-methyl)-benzoylamido]-2-methylphenyl}-4-(3-pyridyl)-2-pyrimidine-amine or a pharmaceutically acceptable salt or crystal form thereof, for the manufacture of a pharmaceutical for stabilizing vulnerable plaques in blood vessels of a subject in need of such a stabilization, for preventing or treating restenosis in diabetic patients, or for the prevention or reduction of vascular access dysfunction in association with the insertion or repair of an indwelling shunt, fistula or catheter in a subject in need thereof.
3. A method for the prevention or reduction of vascular access dysfunction in association with the insertion or repair of an indwelling shunt, fistula or catheter into a vein or artery, or actual treatment, in a mammal in need thereof, which comprises administering to the subject an effective amount of N-{5-[4-(4-methyl-piperazino-methyl)-benzoylamido]-2-methylphenyl}-4-(3-pyridyl)-2-pyrimidine-amine or a pharmaceutically acceptable salt or crystal form thereof.
4. Use, method or composition according to any one of claims 1 to 3, for use in conjunction with one or more active co-agents.
5. Use, method or composition according to any one of claims 1 to 3, for use in dialysis patients.
6. Use, method or composition according to any one of claims 1 to 3, wherein a methanesulfonate salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-(4-pyridin-3-yl)pyrimidin-2-ylamino]phenyl]-benzamide is administered.

7. Use, method or composition according to any one of claims 1 to 3, wherein 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-(4-pyridin-3-yl)pyrimidin-2-ylamino]phenyl]-benzamide or a pharmaceutically acceptable salt or crystal form thereof is administered in a daily dose of 10 mg to 1000 mg.
8. Use, method or composition according to any one of claims 1 to 3, wherein the treatment period commences about 7 days prior to access placement.
9. Use, method or composition according to any one of claims 1 to 3, wherein the vascular access dysfunction is selected from vascular access clotting, vascular thrombosis or restenosis.
10. Use, method or composition according to any one of claims 1 to 3, wherein the vascular access dysfunction is the need for an unclotting procedure.
11. Use, method or composition according to any one of claims 1 to 3, wherein the dosage is administered orally.
12. Use, method or composition according to any one of claims 1 to 3, wherein the subject is selected from a dialysis patient, a cancer patient or a patient receiving total parenteral nutrition.
13. A drug delivery device or system comprising i) a medical device adapted for local application or administration in hollow tubes and ii) a therapeutic dosage of N-{5-[4-(4-methyl-piperazino-methyl)-benzoylamido]-2-methylphenyl}-4-(3-pyridyl)-2-pyrimidine-amine or a pharmaceutically acceptable salt or crystal form thereof, optionally in conjunction with a therapeutic dosage of one or more active co-agents selected from a rapamycin derivative having mTOR inhibiting properties or rapamycin, an EDG-receptor agonist having lymphocyte depleting properties, a cox-2 inhibitor, pimecrolimus, a cytokine inhibitor, a chemokine inhibitor, an antiproliferative agent, a statin, a protein, growth factor or compound stimulating growth factor production that will enhance endothelial regrowth of the luminal endothelium, a matrix metalloproteinase inhibitor, a somatostatin analogue, an aldosterone synthetase inhibitor or aldosterone receptor blocker and a compound inhibiting the renin-angiotensin system,

each being releasably affixed to the drug delivery device or system.

14. A drug delivery device or system comprising i) a medical device adapted for local application or administration in hollow tubes and ii) a therapeutic dosage of N-{5-[4-(4-methyl-piperazino-methyl)-benzoylamido]-2-methylphenyl}-4-(3-pyridyl)-2-pyrimidine-amine or a pharmaceutically acceptable salt or crystal form thereof, optionally in conjunction with a therapeutic dosage of one or more active co-agents selected from a calcineurin inhibitor, mycophenolic acid, 40-O-(2-hydroxyethyl)-rapamycin, rapamycin and midostaurin or a salt thereof or prodrug thereof,

each being releasably affixed to the drug delivery device or system.

15. A drug delivery device or system according to claim 13 or 14, for preventing or treating smooth muscle cell proliferation and migration in hollow tubes, or increased cell proliferation or decreased apoptosis or increased matrix deposition in a subject in need thereof.

16. A drug delivery device or system according to claim 13 or 14, for stabilizing vulnerable plaques in blood vessels, for preventing or treating restenosis, restenosis in diabetic patients or for the prevention or reduction of vascular access dysfunction in association with the insertion or repair of an indwelling shunt, fistula or catheter in a patient in need thereof.

17. A drug delivery device or system comprising i) a medical device adapted for local application or administration in hollow tubes and ii) a therapeutic dosage of N-{5-[4-(4-methyl-piperazino-methyl)-benzoylamido]-2-methylphenyl}-4-(3-pyridyl)-2-pyrimidine-amine or a pharmaceutically acceptable salt or crystal form thereof, optionally in conjunction with a therapeutic dosage of one or more active co-agents, each being releasably affixed to the catheter-based delivery device or system, for use in stabilizing vulnerable plaques in blood vessels, for preventing or treating restenosis, restenosis in diabetic patients or for the prevention or reduction of vascular access dysfunction in association with the insertion or repair of an indwelling shunt, fistula or catheter in a patient in need thereof.

18. A method for preventing or treating smooth muscle cell proliferation and migration in hollow tubes, or increased cell proliferation or decreased apoptosis or increased matrix deposition in a subject in need thereof, comprising local administration of a therapeutically effective amount of N-{5-[4-(4-methyl-piperazino-methyl)-benzoylamido]-2-methylphenyl}-4-

(3-pyridyl)-2-pyrimidine-amine or a pharmaceutically acceptable salt or crystal form thereof, optionally in conjunction with a therapeutic dosage of one or more active co-agents selected from a rapamycin derivative having mTOR inhibiting properties or rapamycin, an EDG-receptor agonist having lymphocyte depleting properties, a cox-2 inhibitor, pimecrolimus, a cytokine inhibitor, a chemokine inhibitor, an antiproliferative agent, a statin, a protein, growth factor or compound stimulating growth factor production that will enhance endothelial regrowth of the luminal endothelium, a matrix metalloproteinase inhibitor, a somatostatin analogue, an aldosterone synthetase inhibitor or aldosterone receptor blocker and a compound inhibiting the renin-angiotensin system.

19. A method for stabilizing vulnerable plaques in blood vessels of a subject in need of such a stabilization comprising the controlled delivery from a drug delivery device or system of a therapeutically effective amount of N-{5-[4-(4-methyl-piperazino-methyl)-benzoylamido]-2-methylphenyl}-4-(3-pyridyl)-2-pyrimidine-amine or a pharmaceutically acceptable salt or crystal form thereof, optionally in conjunction with a therapeutic dosage of one or more active co-agents.

20. A method for preventing or treating restenosis in diabetic patients comprising administering to said patients a therapeutically effective amount of N-{5-[4-(4-methyl-piperazino-methyl)-benzoylamido]-2-methylphenyl}-4-(3-pyridyl)-2-pyrimidine-amine or a pharmaceutically acceptable salt or crystal form thereof, optionally in conjunction with a therapeutic dosage of one or more active co-agents, or the controlled delivery from a drug delivery device or system of a therapeutically effective amount of N-{5-[4-(4-methyl-piperazino-methyl)-benzoylamido]-2-methylphenyl}-4-(3-pyridyl)-2-pyrimidine-amine or a pharmaceutically acceptable salt or crystal form thereof, optionally in conjunction with one or more active co-agents.

21. A method for the prevention or reduction of vascular access dysfunction in association with the insertion or repair of an indwelling shunt, fistula or catheter, or actual treatment, in a subject in need thereof, which comprises administering a controlled delivery from a drug delivery medical device or system of a therapeutically effective amount of N-{5-[4-(4-methyl-piperazino-methyl)-benzoylamido]-2-methylphenyl}-4-(3-pyridyl)-2-pyrimidine-amine or a pharmaceutically acceptable salt or crystal form thereof, optionally in conjunction with one or more active co-agents.